REMARKS

I. Detailed Action

Applicants acknowledge that the information disclosure statement filed on 2/15/06 has been considered. Applicants further acknowledge that a signed copy of the 1449 form is enclosed with this office action.

II. Claim Rejections

A. 35 U.S.C. § 112, second paragraph

Claims 1-12, 23-25, 30-36 and 43-51 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 1-12 and 23-25, the Examiner states "it is not clear how the correlating step of the claim can be accomplished based on the nucleic acid of a single animal. Alternatively, the claim can also be construed as meaning that the 'correlating' step is one of relying a previously known correlation between the marker and a trait, in which case the correlating step does not rely on the establishment of a statistically significant relationship, but instead on 'correlating' the detected allele with this relationship." The Examiner further states that "the recitation 'said animal' in the third line of claim 1 lacks proper antecedent basis."

Applicants have amended independent claim 1 in order to clarify that multiple animals' genetic samples are assayed and that the correlating step is accomplished based on genetic samples from multiple animals. Applicants' amendment also thereby alleviates the antecedent basis rejection. Applicants therefore submit that claims 1-12 and 23-25 are in condition for allowance.

With regard to claims 1-12 and 23-25, the Examiner states that the terms "favorable muscle growth and/or meat quality", "favorable breeding traits", "favorable combination of traits for muscle growth and/or meat quality" and "favorable meat quality" are not clear. The Examiner states that "the claims are indefinite because whether or not a particular trait is favorable is entirely context dependent, and is subjective in nature, it is unclear what the recited polymorphisms are associated with." The Examiner further states that the definition provided in the specification is vague and is a circular definition.

Applicants respectfully traverse this rejection. One skilled in the art would understand from the Specification what the meaning of "favorable" is. The Specification teaches, and one of skill in the art would expect and understand, that favorable meat quality or muscle growth traits is defined by the desired characteristics of the meat. "Favorable" is accordingly defined by the Specification as "a significant increase or decrease (improvement) in one of many measurable meat quality or muscle growth traits (heavy muscling and/or skeletal muscle cramping disease) above the mean of a given population, so that this information can be used to achieve a uniform population which is optimized for meat quality and/ or muscle growth, this may include an increase in some traits or a decrease in others depending on the desired characteristics." (Specification, p. 19). Favorable genetic traits are also described in the specification as traits which are useful in animal breeding as taught by the specification, i.e. breeding traits. (Specification, p. 5). The specification thus teaches the meaning of the terms "favorable muscle growth and/or meat quality", "favorable breeding traits", "favorable combination of traits for muscle growth and/or meat quality" and "favorable meat quality". Applicants therefore submit that claims 1-12 and 23-25 are in condition for allowance.

With regard to claims 30-36, 43-44 and 47-51 the Examiner states that the terms "assaying for the presence of a polymorphism" and "presence of a polymorphism" are indefinite "because it is unclear from the claim how to identify 'the presence of a polymorphism'". The Examiner further states that "a polymorphism is a difference in a nucleotide sequence among individuals, and if one is looking at the genetic material from 'an animal' it is unclear how one would identify a polymorphism within the individual." The Examiner suggests that "amendment of this language to better reflect that it is the presence of a particular allele at a polymorphic site which is correlated with the trait may overcome the rejection."

Applicants respectfully traverse this rejection. The specification teaches that a polymorphism is a genetic means by which a genotype which is indicative of the presence of a particular phenotype can be identified. (*See, e.g.,* Specification, p. 21). However, in an effort to expedite prosecution, Applicants have amended independent claims 30, 47 and 49 with the Examiner's suggested amendment. Claims 30, 47 and 49 now read "presence of an allele characterized by a polymorphism in said gene." Therefore Applicants submit that claims 30-36, 43, 44, and 47-51 are in allowable form.

With regard to claim 50, the Examiner states that the claim is indefinite "because it is unclear what the arbitrary identifiers '1-1, 1-2, and 2-2' mean" and that "the specification does not identify which alleles correspond with the haplotype identifiers."

Applicants respectfully traverse this rejection. The Specification identifies that there are four possible haplotypes when two CKM markers (the 9 base pair insertion/deletion and the MspA1I polymorphism) are used to generate marker genotypes and haplotypes for different populations. (Specification, Example 10, p. 57). According to the Specification, three of the four possible haplotypes were identified. The Specification defines these three haplotypes as "1-

1", "1-2" and "2-2". (Specification, Example 10, p. 57). A description of which alleles correspond with which haplotype identifier is not necessary for purposes of definiteness. It is clear from the claim language and the definition and example in the specification that the claim encompasses the three identified haplotypes when the 9 base pair insertion/deletion and the MspA1I polymorphism are used as marker. The specification thus teaches the meaning of the terms "1-1", "1-2", and "2-2". Applicants therefore submit that claim 50 is in condition for allowance.

B. 35 U.S.C. § 112, first paragraph: Enablement

Claims 1-12, 23-25, 30-36 and 43-51 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not describe in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner states that the claim scope is broad because the claims "are also inclusive of the detection of any possible polymorphism within the CKM gene" and that the entire CKM gene has not been disclosed. The Examiner further states it is statistically unpredictable whether a particular polymorphism is associated with the traits in question and that "no generalized showing exists for even one trait tested among all populations".

Applicants respectfully traverse this rejection. Applicants teach that variation in the creatine kinase-muscle (CKM) gene is associated with favorable muscle growth, favorable meat quality, and breeding traits. The Specification identifies specific polymorphisms that exist within the CKM gene which allow one skilled in the art to select those animals which are likely to produce these desired traits (Specification, pp. 20-21, 34-59).

The Specification teaches that because Applicants have identified these specific polymorphisms in the CKM gene which can be used as markers to identify animals with favorable meat quality traits, muscle growth and breeding traits, one of skill in the art would expect that additional polymorphisms exist within the CKM gene which can be used as genetic markers to identify animals which exhibit these traits. (Specification, p. 33). Contrary to the Examiner's assertions, the specification additionally teaches that the identification of additional polymorphisms in the CKM gene is routine to one skilled in the art and there is ample description in the specification for identification of other polymorphisms. (Specification, p. 21-34). Experimentation is permissible if it is routine and if guidance is provided directing such experimentation such that one skilled in the art would be able to practice an embodiment of the invention. *Ex Parte Forman*, 230 U.S.P.Q 546, 547 (Bd. Pat. App. & Int'f 1986).

The initial step in identifying a polymorphism involves isolation of an animal's DNA. (Specification, p. 21). The DNA is then assayed for the presence of a polymorphism using techniques well known in the art. (Specification, p. 21). The Specification provides a specific example of isolating and identifying a polymorphism within the CKM gene at pages 34-40, 48-57, Examples 1-3 and 9.

Once a polymorphism within the CKM gene has been identified, one skilled in the art would be able to perform routine experimentation in order to associate that polymorphism with favorable muscle growth, favorable meat quality, and/or favorable breeding traits. An example of an association study is provided in the specification. See Example 9, pages 48-57. Accordingly, one of skill in the art would be able to practice Applicants' invention without undue experimentation.

The Examiner further states that the claims are broad because they encompass a wide variety of animal species Furthermore, the Examiner states that "even if homologues of CKM gene were identified and sequenced in other animals, and even if these displayed polymorphisms, it is highly unpredictable as to whether these putative polymorphisms would be indicative of any particular meat traits in animals".

Applicants respectfully traverse this rejection. The Specification teaches that the CKM gene sequence is highly conserved between different species of animals. (Specification, p. 8). The Examiner states that "even if it were conserved in other animals, sequence homology does not predict that the same polymorphisms would be able to be identified in other animal species". However the Specification teaches that one of skill in the art will be able to use variants within the CKM gene as a marker for favorable muscle growth, favorable meat quality, and breeding traits in other animals by using techniques well known to those skilled in the art, such as a BLAST comparison:

> Based upon the highly conserved nature of this gene among different animals and the location of the polymorphisms within these highly conserved regions, is it expected that with no more than routine testing as described herein that these markers can be applied to different animal species to select for meat quality, heavy muscling, and/or skeletal muscle cramping disease based on the teachings herein. Male and female animals of the same breed or breed cross or similar genetic lineage are bred, and the meat quality, heavy muscling, and/or skeletal muscle cramping disease produced by each animal is determined and correlated. For other animals in which sequences are available a BLAST comparison of sequences may be used to ascertain whether the particular allele is analogous to the one disclosed herein. The analogous polymorphism will be present in other animals and in other closely related genes. (Specification, p. 8)

In light of the above remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 1-12, 23-25, 30-36 and 43-51 under 35 U.S.C. § 112, first paragraph.

C. 35 U.S.C. § 112, first paragraph: Written Description

Claims 1-7, 9, 11, 23-25, 30-33, 43-44 and 47-51 stand rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that "all of the current claims encompass the detection of a genus of nucleic acids which comprise CKM polymorphisms which are not disclosed in the specification."

Applicants respectfully traverse this rejection. The Examiner is implicitly requiring that Applicants disclose each member of the claimed genus. This is contrary to the written description requirement. The Federal Circuit has stated that a genus claim may be adequately described where there is a "recitation of structural features common to the members of the genus." *Regents of University of California v. Eli Lilly*, 119 F.3d 1550, 1569 (Fed. Cir. 1997). Moreover, the USPTO's Written Description Guidelines states that a sufficient variety of species has been described to reflect variation within the genus where "one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the member of the genus in view of the species disclosed."

Applicants' claimed invention relates to the association of variance within the CKM gene to the phenotypic traits of favorable muscle growth, favorable meat quality, and breeding traits. Identification of a polymorphism within the CKM gene as a marker for these desired traits is the means by which one practices the invention.

The specification teaches at least three polymorphisms which Applicants have identified that correlate with a phenotypic difference in favorable muscle growth, favorable meat quality, and breeding traits. These polymorphisms are identified in the specification using the restriction

enzymes MspA1I and BamHI, and by a 9 base pair insertion/deletion in the CKM gene. (Specification, Examples 1-3, pages 34-40). One of skill in the art would further recognize that Applicants were in possession of the common attribute within the genus, i.e., the association between the CKM gene and the phenotypic traits of favorable muscle growth, favorable meat quality, and favorable breeding traits.

The Examiner states that "the specification does not provide any written description of what features of a nucleic acid sequence are sufficient to determine that a particular polymorphic position is correlated with these traits". However, the specification teaches that because Applicants have identified at least three specific polymorphisms in the CKM gene, one of skill in the art would expect that additional polymorphisms exist within the CKM gene which can be used as genetic markers to identify animals which exhibit these traits. (Specification, p. 33).

Applicants have therefore adequately described a representative number of species to comply with the written description requirement.

In light of the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 1-7, 9, 11, 23-25, 30-33, 43-44 and 47-51 under 35 U.S.C. § 112, first paragraph.

C. 35 U.S.C. § 102(b)

Claim 47 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Benfield et al. The Examiner states that "'assaying for the presence of a polymorphism' is sufficiently broad so as to encompass any method that identifies the nucleotide(s) present at a particular location in a gene". The Examiner further states that "whether or not Benfield et al. teach that they are identifying a polymorphism, by sequencing the gene of a single individual, they have inherently

determined the nucleotide present at each position, and the allele for any possible polymorphism that exists within the region sequenced."

Applicants respectfully traverse this rejection. In order to alleviate another rejection, claim 47 has been amended to read assaying for the "presence of an allele characterized by a polymorphism in said gene." The specification teaches that a polymorphism is a genetic means by which a genotype which is indicative of the presence of a particular phenotype can be identified. (*See, e.g.,* Specification, p. 21). Benfeld is not assaying for a genotype which is indicative of the presence of a particular phenotype. Nor is Benfield assaying for an allele characterized by a polymorphism. Rather, Benfield is sequencing the promoter region of the rat CKM gene. (Benfield, p. 235-237, Figure 7). This is substantively different than an assay for the presence of an allele characterized by a polymorphism in the CKM gene.

Accordingly, Benfield can not anticipate claim 47. Applicants therefore respectfully request reconsideration and withdrawal of the rejection to claim 47 under 35 U.S.C. § 102(b) as being anticipated by Benfield et al.

D. 35 U.S.C. § 102(a)

Claims 47 and 48 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Korwin-Kossakowaska et al. The Examiner states Korwin-Kossakowaska et al. teach "a method comprising obtaining a pig genomic DNA sample (source/description), and sequencing selected clones. One of the cloned sequences . . . comprises a number of polymorphisms relative to instant SEQ ID NO: 2, but namely, the sequence has a deletion of nine base paris in the second intron of the CKM gene as set forth in SEQ ID NO: 2."

In an effort to expedite prosecution, Applicant has amended independent claim 47 to read "said polymorphism characterized by a 9 bp insertion/deletion of the nucleotide sequence

TGAGCTTCC in intron 2 of said gene". This is a different 9 bp insertion/deletion than that taught by Korwin-Kossakowaska et al., as the Examiner's alignment of the Korwin-Kossakowaska et al. sequence and SEQ ID NO: 2 indicates. Accordingly, Applicants submit that claims 47 and 48 are in condition for allowance.

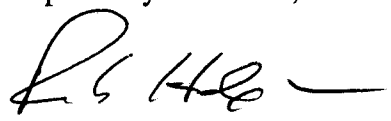
III. Conclusion

In light of the above remarks, Applicants respectfully assert that claims 1-51 are now in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the above rejections. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No other fees are believed to be due in connection with this amendment; however, consider this a request for any inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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